IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

PLANNED PARENTHOOD SOUTHWEST : OHIO REGION, et al., :

:

Plaintiffs, : Case No. 1:15-CV-568

.

v. : Judge Michael R. Barrett

:

RICHARD HODGES,

In his official capacity as the Director of the Ohio Department of Health,

:

Defendant. :

DEFENDANT'S RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Respectfully submitted,

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The crux of this case is a neutral, reasonable, and longstanding health and safety requirement—one that the Sixth Circuit has upheld already. Ohio requires that *all* outpatient surgical facilities have a transfer agreement with a local hospital or an acceptable alternative. Ohio has had this requirement, in some form, since it began regulating outpatient surgical facilities over twenty years ago. *See* Ohio Admin. Code 3701-83-19(E) (originally effective in 1996). During that time, the transfer-agreement requirement has covered facilities where "[o]utpatient surgery is routinely performed." Ohio Rev. Code § 3702.30(A)(1)(a). Thus, it has covered a wide array of outpatient facilities performing many different procedures, including "cosmetic and laser surgery, plastic surgery, abortion, dermatology, digestive endoscopy, gastroenterology, lithotripsy, urology, and orthopedics." *Women's Med. Prof'l Corp. v. Baird*, 438 F.3d 595, 598 n.1 (6th Cir. 2006).

In *Baird*, the Sixth Circuit already upheld Ohio's transfer-agreement requirement, rejecting identical challenges—"undue burden" and "delegation" theories—brought by the same clinic. *Id.* at 602-10. The Court explained that: (1) the transfer-agreement requirement is "neutral," *id.* at 607; (2) the requirement is "a legitimate measure put into place to protect the health of patients," *id.* at 609; and (3) the closure of a single Dayton clinic did "not constitute a substantial obstacle" on women given the availability of other clinics in Ohio, including in Cincinnati, less than an hour away from Dayton, *id.* at 605.

Ohio's transfer-agreement requirement remains constitutional, as no changes in Ohio law, or governing case law, undermine *Baird*. Ohio has since codified its requirement into statute rather than an administrative regulation, but with no material changes that affect this case. And *Baird*'s on-point holding about Ohio's transfer-agreement requirement is not undercut by the Supreme Court's decision invalidating Texas's very different abortion-specific

admitting-privileges laws in *Whole Woman's Health v. Hellerstedt*, 136 S.Ct. 2292 (2016). Indeed, *Hellerstedt*, in invalidating Texas's law, explained that the stricter law there added no net benefit in light of an earlier Texas law—still in place—that is similar to Ohio's. 136 S.Ct. at 2311.

Perhaps most important, *Baird* still controls the common-sense conclusion that the potential closure of once clinic in Dayton does not constitute an undue burden when Ohio has many clinics available within a short drive, including one in Cincinnati. That alone distinguishes *Hellerstedt*, which involved distances many times over what is involved her.

Ohio's interest in ensuring a high standard of medical care for all patients, including women seeking abortions, easily justifies the requirement. The benefits of transfer agreements (which ensure advanced planning between sending and receiving facilities in preparation for emergencies) far outweigh any minimal burden on women seeking abortions (as only one clinic in Ohio lacks a transfer agreement or a variance).

Because Ohio's laws are constitutional and because closing a single clinic—Women's Med Center—will not create an undue burden on women, Plaintiff Women's Med cannot show that it is entitled to a temporary restraining order or a preliminary injunction. Accordingly, the Department respectfully requests that this Court deny Plaintiff's motion.

BACKGROUND

A. Transfer-agreement requirements are not unusual, and Ohio has required them for outpatient surgeries since the 1990s.

Transfer-agreement requirements are common, have long been based on best medical practice across all surgeries, and are not rooted in abortion-specific regulation. Ohio's requirements are best understood in light of (1) the increase in outpatient surgeries during recent

decades and (2) a longstanding federal regulation of outpatient surgical facilities participating in Medicaid.

Outpatient surgery grew rapidly in the 1980s when the federal government expanded Medicare coverage to outpatient procedures. G.D. Durant & C.J. Battaglia, *The Growth of Ambulatory Surgery Centres in the United States*, 1 Ambulatory Surgery 83, 85 (1993), Ex. A. Specifically, in 1982, Congress first approved select outpatient surgical procedures for Medicare reimbursement. *Id.* at 85. By the end of the 1980s, more than 1,200 outpatient surgical facilities were operating across the country. *Id.* at 84.

With the rapid increase in outpatient surgery, safety regulations naturally followed. *Cf.* Madelyn Quattrone, *Is the Physician Office the Wild, Wild West of Health Care?*, 23 J. Ambulatory Care Management 64, 64 (2000), Ex. B (noting concern about a lack of similar "regulatory safeguards" for office-based surgery). The Secretary of Health and Human Services shared draft regulations regarding outpatient surgery centers with the public in March 1982. 47 Fed. Reg. 12574 (March 23, 1982). Within the initial draft, the Secretary included a provision regarding hospital transfer, which was meant "to assure beneficiary access to a hospital in the event of an emergency requiring treatment beyond the capabilities" of the outpatient facility. *Id.* The draft specified that an outpatient surgical facility "must have a written procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities" of the facility. *Id.*

After public input, the Secretary chose to amend, *and strengthen*, the transfer regulation in the final rule. The Secretary clarified the provision "to require an 'effective' procedure for transfer" to a hospital. 47 Fed. Reg. 34082-01 (Aug. 5, 1982). The revised language also specified that a facility "must either have a written transfer agreement with such a hospital, or

each physician with surgical privileges . . . must have admitting privileges at such a hospital."

Id. In describing the purposes of the revised transfer-agreement regulation, the Secretary stressed that the goals of the revised transfer-agreement regulations were to "ensure that patients have immediate access to needed emergency or medical treatment in a hospital" and remain "consistent with our goal of assuring that [Medicare] beneficiaries receive quality care." Id.

The federal transfer regulation remains in place today. It provides:

- (b) Standard: Hospitalization.
 - (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.
 - (2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter.
 - (3) The ASC must
 - (i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or
 - (ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.

42 C.F.R. § 416.41(b).

Following the federal government's lead, Ohio began licensing and regulating outpatient surgical facilities in the mid-1990s. The General Assembly passed a law to establish licensing standards for outpatient surgical facilities (again, called "ambulatory surgical facilities" under Ohio law). S.B. 50, 121st Gen. Assemb. (Ohio 1995) (creating Ohio Rev. Code § 3702.30). The law required that such facilities have licenses and that the Department of Health ("the Department") "establish quality standards for health care facilities," including outpatient surgical facilities. Ohio Rev. Code § 3702.30(B), (E).

The Department set forth regulations for outpatient surgical facilities in January 1996. See Ohio Admin. Code 3701-83. From the outset, these regulations required that each surgical facility "have a written transfer agreement with a hospital for transfer of patients in the event of medical complications, emergency situations, and for other needs as they arise." Id. 3701-83-19(E). As one former Department employee who was involved with the rulemaking process recalled, the transfer-agreement regulation "was not targeted at abortion clinics. It applied to all ASFs." Deposition of Roy Croy at 182:11-12, Ex. C. And, since Ohio was starting from scratch on its regulations, it looked to the federal Medicare regulations. Id. at 183:16-22. Thus, the "genesis" of Ohio's transfer-agreement regulation is the federal standard. Id. These regulations have since been adopted by the General Assembly as statutes. See Ohio Rev. Code § 3702.303. If a facility cannot obtain a transfer agreement, it has the option to seek a variance from the Director, as long as it has backup agreements with doctors who have admitting privileges with a local hospital, so that those doctors can admit patients that need emergency care. Ohio Admin. Code 3701-84-14(B); Ohio Rev. Code § 3702.304.

Although Ohio's regulations were not targeted at abortion clinics, they do apply to them, as they do to all outpatient surgical facilities. Under Ohio law, "ambulatory surgical facility" includes any facility that functions independently from a private doctor's office where "[o]utpatient surgery is routinely performed." Ohio Rev. Code § 3702.30(A)(1). This definition includes abortion clinics. *Founder's Women's Health Ctr. v. Ohio State Dep't of Health*, 10th Dist. Franklin Case No. 01AP-872, 2002 Ohio App. LEXIS 4345, at *23-24 (Ohio Ct. App 2002) (noting that the clinics are "devoted primarily to the performance of outpatient ambulatory surgery as opposed to the diagnosis and treatment of a physician's own patients"). The ASF

regulations do not apply to an abortion clinic that provides only medical abortions. Declaration of Shannon Richey at ¶ 5, Ex. D.

A few years later, Plaintiff Women's Med directly challenged Ohio's transfer-agreement regulation, and the Sixth Circuit ultimately rejected the clinic's challenges to that regulation. Women's Med. Prof'l Corp. v. Baird, 438 F.3d 595, 602-10 (6th Cir. 2006). It stressed that Ohio's regulations were "neutral," applying to "all medical facilities equally, whether they provide abortions or other types of outpatient surgery." Id. at 607. It further concluded that Ohio's regulations "serve a valid purpose, as they ensure that any ASF, and not just those providing abortion services, has a license to operate and meets certain minimum standards." Id.; see also id. at 609 (explaining that "the transfer-agreement requirement" is "a legitimate measure put into place to protect the health of patients").

The Sixth Circuit also held that the closure of Women's Med would "not constitute a substantial obstacle." *Id.* at 605. Rather, the record showed that other abortion clinics would remain "in Cincinnati, Columbus, Cleveland, and Akron." *Id.* Even limiting the inquiry to "Dayton area women seeking an abortion," the Sixth Circuit found "no evidence suggesting that a large fraction of these women would be unable to travel to other Ohio cities for an abortion." *Id.* at 605-06. It likewise rejected the notion that traveling to Cleveland for similar services would be too great a burden for women seeking late-term abortions. *Id.* at 606.

B. Many states and health organizations require or recommend that surgical facilities have transfer agreements because they are beneficial to patients.

Other states also have followed the federal government's lead, requiring outpatient surgical facilities to have transfer agreements (many states accept admitting privileges as an alternative). *See, e.g.*, Ala. Admin. Code r. 560-X-38-.05; Alaska Admin. Code tit. 7, § 12.910(d); Cal. Health & Safety Code § 1248.15(a)(2)(C); Conn. Agencies Regs. § 19-13-D56(e)(7)(B); Haw. Code R.

§ 11-95-31; Ill. Admin. Code tit. 77, § 205.540(d); 410 Ind. Admin. Code 15-2.4-1(e); Kan. Admin. Regs. § 28-34-52b(g); Md. Code Regs. 10.05.05.09; 130 Mass. Code Regs. 423.404; Mo. Code Regs. tit. 19, § 30-30.020(1)(B); Mich. Comp. L. Servs. § 333.20821; Code Miss. R. 15-16-1:42.10; Nev. Admin. Code § 449.996; Ohio Rev. Code § 3702.303(A) (also Ohio Admin. Code 3701-83-19(E)); Okla Stat. tit. 63, § 2666; 28 Pa. Code § 555.23(e); 216 R.I. Code R. § 40-10-5.5.7; S.D. Admin. R. 44:76:04:12; Tenn. Comp. R. & Reg. 1200-08-10-.05(6); 25 Tex. Admin. Code § 135.4(c)(11); Utah Admin. Code r. 432-500-12; 12 Va. Admin. Code §5-410-1240; Wash. Admin. Code §70-230-060; 048-0026-5 Wyo. Code R. § 7(g).

These laws are consistent with the guidelines issued by medical and accreditation organizations and with medical literature. *See* Morris Wortman, *Instituting an Office-Based Surgery Program in the Gynecologist's Office*, 17 J. of Minimally Invasive Gyncol. 673, 681 (2010), Ex. E ("A written transfer agreement with a hospital emergency department is advised if not a requirement in your state. Ideally, the physician should have admitting privileges at the hospital that is intended to be used."). One prominent accrediting organization requires that facilities seeking accreditation have "a written transfer agreement" with a local hospital or that operating surgeons have admitting privileges. Am. Ass'n for Accreditation of Ambulatory Surgery Facilities, 2017 Checklist at 48, available at https://www.aaaasf.org/wp-content/uploads/2019/01/Standards-and-Checklist-Manual-V14.5-01072019.pdf (last visited Aug. 19, 2019).

Similarly, among the American College of Surgeons' core principles are that physicians performing office-based surgeries "have admitting privileges at a nearby hospital, or a transfer agreement with another physician who has admitting privileges at a nearby hospital, or maintain an emergency transfer agreement with a nearby hospital." American College of Surgeons,

Patient Safety Principles for Office-Based Surgery, https://www.facs.org/education/patient-education/patient-safety/office-based-surgery (last visited Aug. 19, 2019). The Federation of State Medical Boards' 2002 model guidelines likewise recommend that doctors performing office-based surgery have a transfer agreement or admitting privileges. Federation of State Medical Boards, Report of the Special Committee on Outpatient (Office-Based) Surgery, available at https://www.fsmb.org/siteassets/advocacy/policies/outpatient-office-based-surgery. pdf (guideline 2G) (last visited Aug. 19, 2019).

Tellingly, the National Abortion Federation's 2018 clinical guidelines also recommend that clinics "consider developing a transfer agreement with a hospital outlining the means of communication and transport and the protocol for emergent transfer of care." National Abortion Federation, 2018 Clinical Policy Guidelines at 54, available at https://prochoice.org/education-and-advocacy/cpg/ (last visited Aug. 19, 2019). Plaintiff Women's Med is a member of the National Abortion Federation. Deposition of Martin Haskell at 18:24-19:2, Ex. F

The medical benefits of transfer agreements are largely commonsense. Preparing for foreseeable medical emergencies is a good thing. This remains true even if such emergencies are uncommon. Outpatient surgeries are generally safe, so physicians can perform them outside the hospital setting. *But* things can, and do, go wrong with such surgeries, sometimes requiring hospital transfers. *See Induced Abortions in Ohio, 2017* at 26-28, Ohio Department of Health (Sept. 2018) (Tables 10a, 10b, 11), Ex. G; Women's Med Ans. to Interog. at 10, 12, Ex. H. And "[h]igh-quality transitions require timely, complete, and accurate information transfer, enabling receiving providers to immediately assume responsibility for patient care." Rebekah Gardner, et al, "Why Is This Patient Being Sent Here?": Communication From Urgent Care to Emergency Department, 50 J. Emerg. Med. 416, 416 (2016), Ex. I. When there are acute medical conditions

and prior evaluation from a clinician, effective communication between the sender and receiver is especially important during emergencies. *Id.* And even Plaintiffs' doctors agreed that "[i]t's best to communicate . . . when there's a surgical emergency so that they know what is going on, as the patient may not be able to communicate that." Deposition of Sharon Liner at 70:8-71:5, Ex. J; *see also* Haskell Depo. at 91:4-17 (stating that communication is important "to inform the receiving physician of the nature of the patient's problem and why they are being transferred and to give them a heads-up that the patient is coming"). Indeed, such communication is "good medical practice." Haskell Depo. at 89:10-90:1.

Having an advanced relationship with the hospital, either through a transfer agreement or backup doctors, allows for better continuity of care. Deposition of Lance Himes at 123:7-21, Ex. K; Deposition of Richard Hodges at 46:16-20, Ex. L ("[A] written transfer agreement ensures the quality and continuity of care for the patient. And it's really an essential part of properly regulating services with patients' health in mind."). And continuity of care provides for the "[c]onsistent communication between providers as well as follow-up care," Liner Depo. at 71:12-15; see also Haskell Depo. at 93:1-8 ("[Continuity of care] means . . . that a patient under treatment, that the care—the treatment that's being provided moves—progresses smoothly in a logical fashion without gaps of care due to lack of knowledge of the patient's treatment and condition."). This is particularly important because hospitals and clinics do not use the same computer software for keeping medical records, and there can be computer software compatibility issues between the medical facilities. Haskell Depo. at 90:13-23. Having a written transfer agreement can address these issues and ensure that the receiving hospital obtains the patient's medical records from the clinic. *Id.* at 90:3-12.

In emergency situations, lack of communication—or miscommunication—can cause medical error and costly delay. *Id.* at 91:18-92:4. Indeed, a lack of communication can "prolong the time it would take the receiving physician to understand the patient's problem and initiate corrective treatment." *Id.* at 91:18-25. And having a transfer agreement in place ensures that the "records are being properly transferred, that there is a physician of record who has taken responsibility for the patient, and that the procedures are worked out in advance . . . so you minimize the risk of mistakes." Hodges Depo. at 47:1-12. Thus, having an advanced plan and agreement in place promotes consistency between transfer procedures, helps future patient handoffs go as smoothly as possible, and is generally a part of good medical practice and the standard of care.

C. Several clinics—throughout Ohio—continue to offer abortion services, including in Cincinnati, which is less than an hour from Dayton.

In Ohio, surgical abortion clinics are spread across six different Ohio counties. *Induced Abortions in Ohio, 2017* at 4 (Figure 3), Ex. G. Excluding Women's Med Center, six different abortion clinics, in six different Ohio cities, satisfy Ohio's surgical licensing requirements. Richey Decl. at ¶ 6. These clinics have been able to satisfy Ohio's requirements in two ways: (1) obtaining a transfer agreement with a local hospital or (2) receiving a variance from the Department's Director. *Id.* ¶ 7.

Five Ohio clinics with active ASF licenses have transfer agreements with nearby hospitals. *Id.* These clinics include Preterm in Cleveland, Planned Parenthood of Greater Ohio (PPGOH) in Columbus and Bedford Heights, Capital Care Network in Toledo, and Northeast Ohio Women's Center in Cuyahoga Falls. *Id.*

Currently, only two clinics are operating without a written transfer agreement—Planned Parenthood of Southwest Ohio (PPSWO), in Cincinnati, and Women's Med Center, in Dayton.

Himes Depo. at 33:8-11, 86:10-23. However, over the years, the Department's Directors, across multiple administrations, have granted several different abortion clinics variances from the transfer-agreement requirement. In *Baird*, for example, the Sixth Circuit recounted four different variances that clinics received before that 2006 decision. 438 F.3d at 608-09. One such clinic was Founder's, a Columbus abortion clinic, which had also been able to obtain variances in recent years. Himes Depo. at 34:4-6. However, Founder's surrendered its ASF license, apparently as a result of a business dispute. *See* Richey Decl. at ¶ 8; Deposition of Terri Hubbard at 20:14-21:10, 62:15-21, Ex. M. Importantly, the variances from Founder's show that there is no four-backup-doctor rule, as Founder's has variances approved with three doctors, all of whom performed surgery at the clinic. 2017 Founder's Variance Grant, Ex. N. Rather, the number of needed backup doctors depends on whether the backup doctors are also the doctors performing the abortions. *See* Himes Depo. 210:4-211:8. Four have been required when the backup doctors are not on staff at the clinic.

PPSWO currently operates under a variance with four backup doctors. 2019 PPSWO Variance Grant, Ex. O. And PPSWO has had little difficulty obtaining backup doctors. Indeed, in 2015, when its variance application was denied because it only had three backup doctors, PPSWO obtained a fourth backup doctor within three days. Sept. 2015 Letter to ODH, Ex. P.

Currently, Plaintiff Women's Med is the only clinic operating without either a transfer agreement or sufficient backup doctors to satisfy the transfer-agreement requirement by an alternate means. (Although, as noted below, that may be changing). Because Women's Med did not satisfy a required health-and-safety regulation—*i.e.* having a transfer agreement or adequate variance—the Department issued an order of proposed license revocation in September 2015. Women's Med Ctr. of Dayton v. State Dep't of Health, 2019 Ohio App. LEXIS 1205, at *3 (Ohio

Ct. App. Mar. 29, 2019). The Department conducted an administrative hearing in April 2016, and the hearing examiner found that the Director's decision to revoke Women's Med's license was valid. *Id.* at *3-4. In November 2016, the Director issued an adjudication order revoking Women's Med's license based on its failure to meet the statutory and regulatory requirement of having a written transfer agreement. *Id.* at *4-6. Women's Med appealed, and both the court of common pleas and the Second District Court of Appeals upheld the revocation. *Id.* at *6, 16, 38. Women's Med sought jurisdiction in the Ohio Supreme Court, but the Court denied review on August 21, 2019, and denied Women's Med's motion for reconsideration on October 29, 2019. *See Women's Med Ctr. of Dayton v. State of Ohio Dep't of Health*, Ohio Supreme Court Case No. 2019-0656. During the appellate process, Women's Med has been operating pursuant to a stay of the revocation order issued by the court of common pleas. *Women's Med Ctr. of Dayton*, 2019 Ohio App. LEXIS 1205, at *7, 23.

Just recently, in June, Plaintiff Women's Med obtained a fourth backup doctor and submitted a renewed variance application. On August 26, 2019, Women's Med submitted an application for a new ASF license. On October 25, 2019, the Department granted Women's Med's variance request, and is working to complete the ASF license application. The new license application is currently pending with the Department. Thus, depending on the outcome of the licensing application, Plaintiff's motion for a temporary restraining order and preliminary injunction will be moot.

D. Ohio clinics have the capacity to accommodate patients from Dayton and the surrounding area.

As noted above, Ohio has six clinics, other than Women's Med, with valid ASF licenses performing abortions. *See supra* at 10. Testimony from some of these clinics shows that they have the capacity to accommodate more abortion patients. In support of its motion, Plaintiff

Women's Med submitted the declarations of several abortion providers. See Pl. Mot. for TRO. Dr. Martin Haskell, owner of Women's Med, testified that his clinic performed 2,129 surgical abortions in the past twelve months, counting back from June 2019. Declaration of Martin Haskell at ¶ 6, doc. 137-3. The medical director of PPSWO, Dr. Sharon Liner, testified that PPSWO could add approximately 800 patients per year. Declaration of Sharon Liner at ¶ 11, doc. 137-4. PPSWO is only 50 miles away from Women's Med. Haskell Decl. at ¶ 46. For PPGOH, its Columbus clinic could accommodate 625 additional patients, and its Bedford Heights clinic could accommodate 500 additional patients. Declaration of Adarsh Krishen at ¶¶ 8, 10, doc. 137-10. The Columbus clinic is only 80 miles from Women's Med. Haskell Decl. at ¶ 46. The Bedford Heights clinic is a bit farther at 213 miles from the Women's Med clinic. See Google maps, Ex. Q. Additionally, Capital Care of Toledo, which is 160 miles from Women's Med, could accommodate 250 patients. Declaration of Terri Hubbard at ¶ 11-12, doc. 137-6. Thus, just four of the six clinics with valid ASF licenses, are able to accommodate 2,175 patients, which is more than the number of surgical abortions performed in one year at Women's Med. And while there is no testimony regarding the remaining two clinics, it is likely they also have capacity to accommodate more patients.

Additionally, some of these Ohio clinics, including the one in Cincinnati, provide late second-term abortions. Women's Med and two other clinics currently provide abortions past 19 weeks 6 days after the last menstrual period ("LMP"). Haskell Decl. at ¶ 11. One, PPSWO in Cincinnati, offers surgical abortions up to 21 weeks 6 days LMP. Liner Decl. ¶ 5. That is as late as Women's Med performs. Thus, even if Women's Med permanently or temporarily closes, women will still have access to abortions, even late term abortions, at other Ohio clinics.

* * *

Plaintiff Women's Med does not have a valid ASF license at this time. Plaintiff lost its appeals that challenged the Department's license revocation order. Because the appellate process ended when the Ohio Supreme Court denied review, the stay of that revocation order has likewise ended. Plaintiff now seeks this Court's intervention to allow it to continue performing surgical abortions without a license. However, Plaintiff has not and cannot meet the high standard required for such a request.

LAW AND ANALYSIS

I. Plaintiff Must Meet a High Standard of Review in Seeking a Preliminary Injunction.

"[A] preliminary injunction is an extraordinary and drastic remedy . . . that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." Mazurek v. Armstrong, 520 U.S. 968, 972 (1997). The movant "bears the burden of justifying such relief," and it is "never awarded as of right." ACLU Fund of Mich. v. Livingston Cnty., 796 F.3d 636, 642 (6th Cir. 2015). Indeed, "the proof required is much more stringent than the proof required to survive a summary judgment motion." Farnsworth v. Nationstar Mortg., LLC, 569 F. App'x 421, 425 (6th Cir. 2014) (quotation and alternation omitted).

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. NRDC, Inc., 555 U.S. 7, 20 (2008). As to the first factor, a plaintiff must establish a "strong" likelihood of success, Jolivette v. Husted, 694 F.3d 760, 765 (6th Cir. 2012) (quotation omitted); a mere "possib[ility]" of success does not suffice, Summit Cnty. Democratic Cent. & Exec. Comm. v. Blackwell, 388 F.3d 547, 551 (6th Cir. 2004). Similarly, the plaintiff must show a

likelihood, not just a possibility, of irreparable injury. *Winter*, 555 U.S. at 22. As discussed more fully below, Plaintiff here fails on all counts.

II. Plaintiff Women's Med Does Not Show that It Is Likely to Succeed on the Merits

Plaintiff brings two challenges to Ohio's transfer-agreement law as it has been applied to Women's Med—that it creates an undue burden for women seeking abortion and that it is an unconstitutional delegation of power—however, neither has merit. As explained below, the benefits of transfer agreements, in particular continuity of care, outweigh any burden on women if Women's Med closed. Furthermore, even if the delegation doctrine is still valid law, Ohio's transfer agreement and backup-doctor provisions do not constitute an unconstitutional delegation of authority. Because Plaintiff Women's Med is unlikely to succeed on the merits of either claim, this Court should deny Plaintiff's motion for a temporary restraining order and preliminary injunction.

A. Closing Women's Med would not create an undue burden for women in Ohio.

Unlike the laws in some states (and like the laws in others), Ohio's transfer-agreement law is not abortion specific but is generally applicable to all ASFs. *See Women's Med. Prof'l Corp. v. Barid*, 438 F.3d 595, 603, 607 (6th Cir. 2006) (noting that Ohio's transfer-agreement requirement was a "generally applicable and neutral regulation"). Even though Ohio's law is generally applicable, the Sixth Circuit has held that, because the law affects abortion clinics,

¹ Both the transfer-agreement requirement and variance statute apply to all Ohio ASFs, not just abortion clinics. The only abortion-specific law that Women's Med cites is Ohio's law barring public hospitals from entering into transfer agreements with abortion clinics. However, that law does not affect Women's Med, as no public hospital is within 30 miles of Women's Med, and a transfer agreement must be within 30 miles of the ASF.

courts should apply the undue burden test set forth in *Planned Parenthood v. Casey*, 505 U.S. 833, 876 (1992).²

Under *Casey*, laws regulating abortion are unconstitutional if they have "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." 505 U.S. at 877 (plurality op.). To assess whether a burden is "undue," courts must "consider the burdens a law imposes on abortion access together with the benefits those laws confer." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016). However, "the fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." *Gonzales v. Carhart*, 550 U.S. 124, 157-58 (2007) (quotation and alteration omitted).

More important and contrary to Plaintiff's assertion, *Hellerstedt* does not undermine *Baird*'s holding that Ohio's transfer-agreement law does not create an undue burden. To be sure, *Hellerstedt* provides the framework for analyzing abortion-specific health-and-safety regulations, but its analysis was bound by the facts and realities in Texas. 136 S.Ct. at 2310-14 (conducting a fact-intensive inquiry based on the district court's findings). Ohio is not Texas. Transfer agreements are not admitting privileges. Indeed, *Hellerstedt* found Texas's stricter laws unnecessary in part because Texas already had a valid law requiring clinics to have a "working arrangement with a doctor with admitting privileges," 136 S.Ct. at 2311—in other words, something akin to either of Ohio's options. And of course, the two-or three hours' drive across West Texas, with many clinics closing and creating a large drop in access, is far different from the short hop from Dayton to Cincinnati. Those distinctions make all the difference.

² The Department preserves for appeal the argument that *Casey*'s undue burden test does not apply to generally applicable laws but only to laws that provide specific regulations on abortions.

1. The undue-burden test and generally applicable laws

The Supreme Court has held that women have a constitutional right to obtain an abortion before viability. *See Casey*, 505 U.S. 833. But it has never held that states must *facilitate* the provision of abortions. For example, states are under no obligation to pay for abortions by those who cannot otherwise obtain them. *Rust v. Sullivan*, 500 U.S. 173, 201 (1991). Nor should they be obligated to facilitate abortions by carving out exceptions to generally applicable health-and-safety regulations. It follows, then, that states do not run afoul of *Casey* by having abortion clinics to operate under the same transfer-agreement requirements as everyone else.

These principles are not unique to abortion law. The First Amendment protects the freedom of the press. But it does not violate the First Amendment to subject newspaper publishers to the same property taxes as all other business owners. *See Minneapolis Star & Tribune Co. v. Minnesota Comm'r of Revenue*, 460 U.S. 575, 581 (1983) ("It is beyond dispute that the States and the Federal Government can subject newspapers to generally applicable economic regulations without creating constitutional problems."). Nothing about the analysis would change if, due to market conditions, the only newspaper in town could not afford the tax.

The same reasoning should apply in the abortion context. Otherwise, Plaintiff Women's Med could claim exemptions from any number of regulations merely because enforcement might affect abortion access. It could avoid paying the same burdensome taxes that would put the aforementioned newspaper out of business—leading to the oddity that the indirect-beneficiaries of the right to an abortion (abortion doctors) get more protection than the intended beneficiaries (the press) of a right enumerated in the First Amendment. This, however, would be absurd. The better answer is that neutral, generally applicable laws that serve a legitimate state interest survive constitutional scrutiny even if they have some effect on the underlying right.

And, as noted, Ohio's transfer-agreement law and variance process are generally applicable neutral laws. Ohio is not like Texas where the laws imposed more stringent requirements on abortion clinics than on other facilities. *See Hellerstedt*, 136 S.Ct. at 2300. As Justice Ginsburg observed, Texas engaged in a "targeted regulation of abortion providers." *Id.* at 2321 (Ginsburg, J., concurring); *see also Planned Parenthood of Wis., Inc. v. Van Hollen*, 94 F. Supp.3d 949, 965 (W.D. Wis. 2015) ("[D]efendants conceded that an admitting privileges requirement ha[d] never been imposed on *any* outpatient procedure other than the provision of abortion services."); *Planned Parenthood SE, Inc. v. Strange*, 33 F. Supp. 3d 1330, 1336 (M.D. Ala. 2014) (addressing statute that imposed new requirements on "abortion clinics"). While one abortion clinic may close as a result of Ohio's neutral, generally applicable law, this does not mean that Ohio's law is unconstitutional.

2. Ohio's transfer-agreement requirement promotes health and safety by providing for continuity of care in the event of an emergency

Requiring transfer agreements or backup doctors is not the same as requiring abortion providers to have admitting privileges. And while Plaintiff contends that there are no benefits to transfer agreements, the federal government, numerous health organizations, and even the National Abortion Federation disagree. See supra at 3-4, 6-8. Indeed, even the Supreme Court disagrees. In striking Texas's admitting-privileges law, the Court "found nothing in Texas' record evidence that shows that, compared to prior law (which required a 'working arrangement' with a doctor with admitting privileges), the new law advanced Texas' legitimate interest in protecting women's health." Hellerstedt, 136 S.Ct. at 2311 (emphasis added). The Court did not conclude that requiring an arrangement to ensure continuity of care had no benefit, it merely concluded that admitting privileges did not add to the benefit of having backup doctors in the case of an emergency.

Ohio "has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that insure maximum safety for the patient." *Id.* at 2309. In *Baird*, the Sixth Circuit already considered the constitutionality of Ohio's transfer-agreement regulation, which applied then (and applies now) to all outpatient surgical facilities. 438 F.3d at 602–10. These regulations, the Court held, "serve a valid purpose; they ensure that any [surgical facility], and not just those providing abortion services, has a license to operate and meets certain minimum standards." *Id.* The Court further recognized that Ohio's transfer-agreement regulation was "a legitimate measure put into place to protect the health of patients." *Id.* at 609. And *Baird* remains good law because it is directly on-point, and *Hellerstedt*'s invalidation of a very different Texas law does not change that. Indeed, the Sixth Circuit recently reaffirmed *Baird* by positively citing it alongside *Hellerstedt* in another abortion-related case. *See Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 916 (6th Cir. 2019).

The parties agree that having continuity of care and ensuring that accurate information is provided to a transferring hospital in the case of emergencies are best medical practices. *See supra* at 8-10. Courts likewise have recognized the importance of "ensuring that a doctor has enough information about the initial procedure to make wise choices about the patient's care." *Planned Parenthood SE, Inc. v Strange*, 30 F. Supp. 3d 1330, 1371 (M.D. Ala. 2014). As one court noted, continuity of care is "paramount in managing complications." *Planned Parenthood of Wis., Inc. v. Van Hollen*, 94 F. Supp. 3d 949, 973 (W.D. Wis. 2015).

While rare, complications from outpatient surgery do occur. Even in the abortion context, there are circumstances, such as uterine perforation or an allergic reaction, when a receiving physician would need additional information from the abortion provider in order to make the best decisions about the patient's care. *Strange*, 30 F. Supp. 3d at 1371. Preparing for

these foreseeable emergencies is part of the standard of care. Indeed, the National Abortion Federation, to which Plaintiff Women's Med is a member, requires that "[p]rotocols for the management of medical emergencies must be in place." 2018 NAF Clinical Guidelines at 54. As part of this requirement, the organization *recommends* that clinics "consider developing a transfer agreement with a hospital outlining the means of communication and transport and the protocol for emergent transfer of care." *Id*.

The district court in Wisconsin, which was very critical of the state's admitting-privileges law, discussed the importance of transfer agreements. *Van Hollen*, 94 F. Supp. 3d at 973. The court specifically noted that "there was a consensus *among the parties and their experts* that *advance transfer agreements* and a call to the receiving hospital's emergency department from the physician who performed the abortion are the *most important factors* in ensuring continuity of care." *Id.* at 973 (emphasis added); *see also id.* at 976-77 (noting that "transfer agreements already ensure continuity of care").

The evidence and prior court findings show that transfer agreements and backup doctors ensure continuity of care, and thus, provide a benefit to all patients seeking outpatient surgery, including women seeking abortions. While Plaintiff provides the opinion of others who disagree, this at best shows that there is some disagreement within the medical community regarding the best method of ensuring continuity of care. However, transfer agreements fall within the range of acceptable arrangements. *See Strange*, 30 F. Supp. 3d at 1364-65, 1372 (detailing the different approaches, including having backup doctors, and finding only the admitting-privileges approach to be outside the acceptable range). Medical disagreement "does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts." *Gonzales v. Carhart*, 550 U.S. 124, 164 (2007).

Furthermore, contrary to Plaintiff's assertions, the existence or non-existence of a written transfer agreement or backup agreements can affect the quality of care a patient receives, despite the Emergency Medical Treatment and Active Labor Act ("EMTALA"). Just because hospitals might be obligated to treat patients under certain scenarios does not mean that transfer agreements are unnecessary. After all, the federal government has not repealed its transfer-agreement requirement for all Medicare-eligible facilities in light of EMTALA. The point of EMTALA is to ensure that patients will not be ignored or dumped on other healthcare facilities. See Bryan v. Rectors & Visitors of Univ. of Va., 95 F.3d 349, 351 (4th Cir. 1996). But the point of Ohio's written transfer-agreement law and variance requirements are to ensure that healthcare facilities will implement measures to help emergency transfers from one to another go as smoothly and safely as possible. While EMTALA might obligate hospitals to treat patients, it—unlike transfer agreements—does nothing to ensure an improved patient outcome. Accordingly, Plaintiff's EMTALA argument is unavailing.

For these reasons, Ohio's transfer-agreement law and variance requirements provide a needed health benefit to all outpatient surgical patients, including women seeking abortions. Ohio's law ensures continuity of care in the case of an emergency and that the receiving hospital has the needed information to treat the emergency. While *Hellerstedt* said that requiring admitting privileges for the doctors performing abortions did not have any added benefit to patients—again, in light of prior Texas law requiring a "working arrangement" with a doctor with such privileges—transfer agreements and backup doctors are not the same. Indeed, they are both similar to the prior Texas law that *Hellerstedt* cited approvingly. Rather, such agreements advance Ohio's interest in ensuring the health and safety of its citizens.

3. Ohio's transfer agreement and variance provisions do not create an undue burden

As discussed above, Ohio's regulatory measures provide a significant benefit to outpatient surgical patients by ensuring continuity of care. However, even if the transfer-agreement law provided only a minimal benefit, to prevail on their challenge, Plaintiff must prove that the transfer agreement and variance requirements pose an undue burden. *See, e.g.*, *June Med. Servs., L.L.C. v. Gee*, 905 F.3d 787, 803 (5th Cir. 2018) ("[E]ven regulations with a minimal benefit are unconstitutional only where they present a substantial obstacle to abortion."); *Jackson v. Women's Health Org. v. Currier*, 320 F. Supp. 3d 828, 841 (S.D. Miss. 2018) (upholding a law, even though it provided no demonstrated benefit because the plaintiffs had not factually shown a burden). Specifically, Plaintiff must show that the regulatory measures place a "substantial obstacle in the path of a woman seeking an abortion." *Casey*, 505 U.S. at 878. Such an analysis requires a fact-intensive review, and whether a law imposes an undue burden depends upon the precise effects of a law in any given case.

Both *Baird* and *Hellerstedt* illustrate the fact-intensive nature of the undue-burden analysis. In *Baird*, the Court applied the facts in the record to determine that Ohio's transfer-agreement requirement at issue did not create an undue burden because, despite the law having the effect of closing Dayton's only local abortion clinic, women in the Dayton area could still obtain abortions in at least four other cities, including one clinic just 45 to 55 miles from the Dayton clinic. 438 F.3d at 605. The Court upheld the transfer-agreement rule "even though it would close the only clinic providing late second trimester abortion services in southern Ohio because women could still obtain this type of abortion in Cleveland or at other clinics providing this type of service." *Id.* at 607.

Plaintiff argues that Baird must be reconsidered in light of Hellerstedt. But the facts in Texas are not the facts in Ohio. In Hellerstedt, the Supreme Court held that Texas's admitting-privileges law imposed an undue burden on women seeking an abortion. 136 S.Ct. at 2310-14. Before the disputed regulation, there were 40 abortion clinics in Texas. *Id.* at 2301. Leading up to the enforcement of the regulation, the number dropped "by almost half," and if the provision took effect the number of clinics would have dropped to 7 or 8. Id. Women in Texas—a geographically massive state—were forced to travel far greater distances to obtain abortions. Id. at 2316. The Court recognized that "increased driving distances do not always constitute an 'undue burden,'" but looked at the increased driving distance as "but one additional burden, which, when taken together with others that the closings brought about, and when viewed in light of the virtual absence of any health benefit," amounted to an undue burden. Id. (citations omitted). The Court found that after the law went into effect, the "number of women of reproductive age living in a county . . . more than 150 miles from a provider increased from approximately 86,000 to 400,000 . . . and the number of women living in a county more than 200 miles from a provider from approximately 10,000 to 290,000." *Id.* at 2313.

These facts simply do not apply in Ohio. *First*, Texas is much larger than Ohio. Texas's law would have closed thirty-plus clinics and left some women many hundreds of miles away from the nearest abortion clinic. *Id.* at 2301, 2313. Here, Plaintiff contends only that one clinic faces closure under Ohio's laws. Ohio will still be home to six other fully operational clinics, even if Women's Med is forced to close. *See supra* at 10. Indeed, if there are women in Ohio that live further than 150 miles away from an abortion clinic, closing Women's Med will not change that number because three clinics surround Dayton that are within 150 miles away. *Id.* Dayton is approximately 50 miles away from the Cincinnati clinic and 80 miles away from the

Columbus clinic. *Id.* And while, the Toledo clinic is approximately 160 miles from Women's Med, women who live north of the clinic would be within 150 miles of the Toledo clinic. *Id.* Thus, closing Women's Med does not increase the number of women living more than 150 miles from a provider, unlike in Texas.

And with regard to abortions in the late second trimester, the facts now are better than when *Baird* was decided. In 2006, there were only two clinics providing late abortions—Women's Med and a Cleveland clinic. *Baird*, 438 F.3d 607. The Court held that, even if Women's Med closed, having to drive to Cleveland would not be an undue burden. *Id.* Now, there are three clinics that provide late abortions. Haskell Decl. at ¶ 11. In addition to the Cleveland clinic, PPSWO in Cincinnati now offers surgical abortions up to 21 weeks 6 days LMP. Liner Decl. at ¶ 5. Thus, with the addition of a clinic in southern Ohio, the driving distance for women seeking late-term abortions is *less* than the distances that the Sixth Circuit already approved in *Baird*.

Furthermore, as noted above, Ohio's law applies generally to all ASFs and is not targeted at abortion clinics, unlike Texas's law. Indeed, the Supreme Court specifically stated that "the fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." *Gonzales v. Carhart*, 550 U.S. 124, 157-58 (2007) (quotation and alteration omitted). Thus, even if the incidental effect of the law is that women will have to travel farther, this effect does not invalidate the law.

Second, transfer agreements are not admitting privileges. The laws at issue in Hellerstedt were more stringent than Ohio's transfer agreement and variance laws. Texas required, for example, that every doctor providing abortions have admitting privileges with a nearby hospital.

Hellerstedt, 136 S.Ct. at 2300. Ohio's law requires each clinic to have a written transfer agreement with a local hospital—a requirement for every ambulatory surgical facility in the state—or, if the clinic is unsuccessful in doing so, to obtain a variance by recruiting doctors who have admitting privileges at a local hospital.

In *Hellerstedt*, the admitting-privileges requirement was particularly burdensome because of the conditions hospitals have for granting privileges. *Id.* at 2312. For example, many hospitals "condition admitting privileges on reaching a certain number of admissions per year," but abortion providers are usually unable to meet this requirement. *Id.* Other hospitals have clinic data or residency requirements, and some academic hospitals require clinicians to have faculty appointments. *Id.*; *see also Strange*, 33 F. Supp. 3d at 1344-46 (discussing the requirements for admitting privileges).

However, there is no such evidence here. There is no evidence that hospitals condition transfer agreements on the number of admissions per year, residency, clinic studies, faculty appointments, or any other factor. Indeed, only two of the eight abortion clinics are operating without transfer agreements. *See supra* at 10-11. And the variance procedures also do not require that abortion providers obtain admitting privileges, they merely need to contract with physicians who *already* have privileges, and therefore, *already* meet the hospitals requirements for privileges. While one clinic—Plaintiff Women's Med—has not obtained a variance, this is a far cry from the admitting-privileges requirement in Texas that would have caused the closure of over three-fourths of the clinics. And again, after years of saying that they could not obtain a fourth doctor, after they lost two rounds in state court and faced a final loss, Women's Med managed to do it. (Similarly, a Toledo abortion clinic obtained a transfer agreement just days after losing an Ohio Supreme Court case about its licnese).

Third, the Court in Hellerstedt considered that, after the regulation took effect, the remaining clinics would have had to increase their capacity from 14,000 abortions annually to 60,000 to 70,000 to meet the demand. 136 S.Ct. at 2316. Again, Ohio is not Texas. Six clinics with valid ASF licenses perform surgical abortions in Ohio. See supra at 10. Testimony from some of these clinics shows that they have the capacity to accommodate Women's Med's patients. Dr. Haskell, who owns Women's Med, testified that his clinic performed 2,129 surgical abortions in the past year. Haskell Decl. at ¶ 1, 6. The evidence submitted by the Plaintiff shows that the remaining clinics can accommodate these patients. Capital Care of Toledo can accommodate 250 additional patients. Hubbard Decl. at ¶¶ 11-12. The PPGOH clinic in Columbus could accommodate 625 additional patients, and its clinic in Bedford Heights could accommodate 500 additional patients. Krishen Decl. at ¶¶ 8, 10. And PPSWO could add approximately 800 more patients per year. Liner Decl. at ¶ 11. These clinics could, in sum, accommodate up to 2,175 additional patients, more than the number of abortions performed by Dr. Haskell. And, these numbers do not take into account the other two clinics that could likely add patients. Therefore, unlike in Texas, Ohio's remaining clinics can cover the additional patients if Women's Med closes, including a clinic less than an hour away

Contrary to Plaintiff's assertion, *Hellerstedt* does not undermine *Baird*'s holding that Ohio's transfer-agreement law does not create an undue burden. Rather, *Hellerstedt* provides the framework for analyzing abortion-specific health-and-safety regulations and illustrates that an undue burden analysis is bound by the facts and realities in each state. 136 S.Ct. at 2310-14 (conducting a fact intensive inquiry based on the district court's findings); *see also June Med. Servs.*, 905 F.3d at 803 (recognizing that the Fifth Circuit was bound by *Hellerstedt*, but that the present case involved a similar statute, but greatly dissimilar facts and geography). Whether a

law imposes an undue burden depends upon the precise effects of a law in any given case, and the nature of the burden must be assessed with regard to the particular facts on the ground. Under *Hellerstedt*, no one factor, including driving distance, is determinative. And, a state's specific geography and population must be considered in this analysis. This necessarily means that the same law may be constitutional in one state even if it imposes an undue burden in another.

Under *Baird*, Plaintiff cannot show that the transfer agreement and variance requirements pose a substantial obstacle to a woman seeking an abortion; the closure of a single clinic in Dayton does not constitute an undue burden. *Baird* rejected the same undue burden challenge that Plaintiff brings here and is dispositive.

* * *

Ohio's transfer agreement and variance provisions provide a significant medical benefit by ensuring continuity of care. At the same time, these provisions do not pose a substantial obstacle to women seeking abortions. If there is any burden associated with the provisions, it does not rise to the level of being an undue burden. *Baird*, 438 F.3d at 605. Weighing the significant medical benefits versus the minimal, if any, burden on women, Ohio's transfer agreement and variance provisions are constitutional.

B. Ohio's written transfer-agreement requirement does not unconstitutionally delegate authority, as the ultimate decision remains with the Ohio Department of Health.

Plaintiff makes a limited and incorrect claim that Ohio's transfer-agreement law and variance provisions are an "unconstitutional delegation" of authority to private "hospitals and physicians." Pl. PI Mot. at 27-28. However, the Sixth Circuit already upheld the transfer-agreement regulations in the face of a delegation challenge, *see Baird*, 438 F.3d at 610; nothing

in the statute changes that result. For this and other reasons, Plaintiff's delegation argument fails.

1. The Supreme Court has not found an unconstitutional third-party delegation since the 1930s.

The doctrine of third-party delegation is a hybrid of *Lochner v. New York*, 198 U.S. 45 (1905) and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 540 (1935). It uses due process and Article I to challenge provisions when they allow private parties to exercise arbitrary legislative power. *See Dep't of Transp. v. Ass'n of Am. R.Rs.*, 135 S. Ct. 1225, 1228 (2015). But by the end of the 1930s, the Supreme Court had significantly constricted the doctrine. It explained that if "Congress had the power to" act "without the approval of anyone," then it certainly had the power to make its action contingent on private action. *See United States v. Rock Royal Co-op*, 307 U.S. 533, 577-78 (1939) (upholding law allowing the Department of Agriculture to change minimum milk prices only if regional milk producers approved the change).

Little has changed on this issue since 1940. Take *New Motor Vehicle Board of California v. Orrin W. Fox Co.*, 439 U.S. 96 (1978), which upheld an automobile franchise law that delayed establishment of a new franchise location if any existing franchisee filed a protest. Even though authority was delegated to the new location's direct competitor, the Court found that the scheme was not "an impermissible delegation of state power to private citizens," noting that "[a]lmost any system of private or quasi-private law could be subject to the same objection." *Id.* at 108-09.

2. Ohio's transfer-agreement requirement is not an unconstitutional delegation of state power to private actors

Ohio has the authority to set emergency safety requirements for medical facilities, and it does not entrust that law-making authority to private parties. The delegation doctrine is

concerned with who is exercising legislative authority and whether they may lawfully do so. Here, the General Assembly, not hospitals and doctors, exercised lawmaking authority by requiring *all* ambulatory surgical facilities to have a transfer agreement, which it had authority to do. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (noting that the states have "great latitude under their police power to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." (quotation omitted)); *Simopolous v. Virginia*, 462 U.S. 506, 516 (1983) ("[T]he State necessarily has considerable discretion in determining standards for the licensing of medical facilities.").

The role of hospitals and doctors is limited, and at no time do either the private hospitals or doctors write statutes or regulations. Under the already-written statute, hospitals and doctors simply supply a service—emergency care—to health care facilities. This is no different than any other provider of goods and services, such as those supplying a backup generator, anesthesia, or resuscitation equipment. *See* Ohio Adin. Code 3701-83-19 to -20. It is in no way an exercise of the legislative power vested in the General Assembly. And Plaintiff's attempt to expand the delegation doctrine beyond concerns about vesting *legislative* power in the wrong hands fails. At its core, the doctrine concerned legislatures delegating *lawmaking* power to private parties. Expanding that doctrine beyond its separation-of-powers roots would, as the Supreme Court said in refusing to expand the doctrine, threaten "[a]lmost any system of private or quasi-private law." *New Motor Vehicle Bd. of Cal.*, 439 U.S. at 109.

Furthermore, that surgical facilities must satisfy health-and-safety requirements does not transform their licensing into some delegated private veto. A surgical facility—like most health care facilities—must establish access to "medical care beyond the level the [surgical] facility can provide" when such care "is necessary." Ohio Rev. Code § 3702.304(B)(2). Providers of

ambulatory procedures may provide such care themselves (and be licensed as a hospital), or they can show access to a hospital or physician who can provide such emergency care (and be licensed as a surgical facility). Even in the *Lochner* era, the Court rejected challenges to state medical regulations, explaining that "[f]ew professions require more careful preparation by one who seeks to enter it than that of medicine." *Dent v. West Virginia*, 129 U.S. 114, 122 (1889); *see Collins v. Texas*, 223 U.S. 288, 294-98 (1912). A state may "prescribe all such regulations as in its judgment will secure or tend to secure [its citizens] against the consequences of ignorance and incapacity" in those who practice medicine. *Dent*, 129 U.S. at 122.

Nor does the analysis differ because some surgical facilities perform abortions. As with any medical procedure, the state has "legitimate interests from the outset . . . in protecting the health of" the patient. *Baird*, 438 F.3d at 603 (quotation omitted). And a transfer-agreement requirement "is a legitimate measure put into place to protect the health of patients." *Id.* at 609. Importantly, no federal circuit court has ever used delegation to invalidate an abortion statute. *See Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 748 F.3d 583, 600 (5th Cir. 2014); *Baird*, 438 F.3d at 610; *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 556 (9th Cir. 2004); *Greenville Women's Clinic v. Comm'r*, *S.C. Dep't of Health & Envtl. Control*, 317 F.3d 357, 362 (4th Cir. 2002); *Women's Health Ctr. of W. Cnty., Inc. v. Webster*, 871 F.2d 1377, 1382 (8th Cir. 1989) (noting admitting-privileges requirement is no different than licensed physician requirement). If Ohio's law was an unlawful delegation to hospitals and physicians, then the same would be true of requiring a licensed doctor at all, which necessarily "involves the independent action of a medical licensing board." *Webster*, 871 F.2d at 1382. Yet, the Supreme Court has expressly upheld such requirements even in the abortion context. *Mazurek v.*

Armstrong, 520 U.S. 968, 969 (1997). Requiring access to emergency facilities (as Ohio does) or access to a licensed doctor (as in *Mazurek*) is not a "veto" of the right to an abortion.

Furthermore, even if delegation were a viable doctrine in this context (it is not), and even if the transfer-agreement requirement was an unlawful delegation (it is not), that would not end the matter. As the Sixth Circuit explained in *Baird*, Plaintiff's claim fails because the Director retained the ultimate authority to grant clinic licenses, so "area hospitals do not necessarily have the final veto on whether an abortion clinic is licensed." 438 F.3d at 610. And none of Women's Med's claims about the changes in Ohio law from *Baird* until now make a difference. Indeed, the Ohio Supreme Court held that it did not need to review a challenge that focused only on the newer statutes because the transfer-agreement statute merely codified the prior regulation upheld in *Baird*. *Capital Care Network of Toledo v. Ohio Dep't of Health*, 106 N.E.3d 1209, 1217-18 (Ohio 2018).

Women's Med's focus on the variance statute, which ties the process to backup doctors and removes the possibility of waivers, is mistaken. It is true that *Baird* held that it "need not" even reach delegation because the Director ultimately "retains authority to grant a waiver" of the transfer-agreement requirement. 438 F.3d at 610. However, stopping there and finding a violation of the delegation doctrine would ignore reality. Even at the time of *Baird*, the regulations allowed variances only if the transfer-agreement purpose was "met in an alternative manner," and waivers only if doing so would "not jeopardize the health and safety of any patient." 438 F.3d at 599. In practice, the Department had long required "the names of the backup physicians, their credentials, and admitting privileges at" local hospitals. *Id.* at 602. Thus, when *Baird* was decided, clinics in Ohio needed to either have a transfer agreement or a variance application with sufficient backup doctors. And the Sixth Circuit found no delegation problem.

Nothing has changed. Today, clinics still need either a transfer agreement or backup doctors, and the Director still ultimately grants or denies a facility's license.

Additionally, while Women's Med also cites the new statutory limit on public hospitals entering into transfer agreements with abortion clinics, no public hospital is within the relevant radius of Women's Med. So, that law does not affect them.

III. The Remaining Preliminary Injunction Factors Favor the State.

Balancing the potential harm to Plaintiff against the risk of harm to others and the public interest confirms that Plaintiff's motion should be denied.

First, contrary to Plaintiff's assertions, Ohio's transfer-agreement provisions do not implicate rights of either Dr. Haskell or Women's Med. The Sixth Circuit recently held that clinics and doctors do not have a "right to perform abortions." *Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 912 (6th Cir. 2019). Rather, any status held by the clinics is *derivative* of the woman's rights. *Id*.

Second, as explained above, the provisions also do not create an undue burden for Women's Med's patients. *See supra* at 21-27. Even if Women's Med closed, women in the area have access to other clinics, and the driving distances to those clinics do not constitute an undue burden. *Baird*, 438 F.3d at 605. Furthermore, any inconvenience to patients is outweighed by the risks to Ohio ASF patients if the preliminary injunction is granted. Again, the challenged provisions exist precisely to ensure the safety and health of patients undergoing surgical procedures at facilities that lack an agreement with a hospital to ensure the safe and prompt transfer of patients in need of heightened care.

Additionally, an injunction would subject the State to ongoing irreparable harm. As various Supreme Court justices have recognized, "[a]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable

injury." *Maryland v. King*, 133 S.Ct. 1, 3 (2012) (Roberts, C.J., in chambers) (quoting *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, C.J., in chambers)). So, too, does the public have an interest in the validity and enforceability of its duly enacted laws. *Tri-Cnty. Wholesale Distribs., Inc. v. The Wine Grp., Inc.*, No. 2:10-cv-693, 2010 WL 3522973, at *8 (S.D. Ohio Sept. 2, 2010).

Thus, balancing the important interest in patient safety against the Plaintiff Women's Med's purported harm, weighs in favor of the denying preliminary injunctive relief.

CONCLUSION

For the reasons explained above, this Court should deny Plaintiff Women's Med's motion for a temporary restraining order and preliminary injunction.³

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³ Because the Department has granted Women's Med's variance request, the transfer-agreement provision does not impact whether the clinic gets a new license. If the clinic passes the health-and-safety inspection that is required of all ASFs in Ohio, and which is currently being scheduled, then the Department would grant the clinic a new license. Thus, at most, Women's Med would only be unable to perform surgical abortions until it passes the standard health-and-safety inspection. If this Court believes that such a result would be an undue burden, then a temporary restraining order would be sufficient, as it is possible the clinic could again be licensed to perform surgical abortions before the order would expire.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing was electronically filed with the U.S. District Court, Southern District of Ohio, on October 29, 2019, and served upon all parties of record via the court's electronic filing system.

s/ Tiffany L. Carwile

TIFFANY L. CARWILE (0082522) Assistant Attorney General